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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,618	09/05/2003	Orlando Petrini	1/1526	8012
28501	7590	12/14/2004	EXAMINER	
BOEHRINGER INGELHEIM CORPORATION 900 RIDGEBURY ROAD P. O. BOX 368 RIDGEFIELD, CT 06877			MCCORMICK EWOLDT, SUSAN BETH	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 12/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/656,618

Applicant(s)

PETRINI ET AL.

Examiner

Susan B. McCormick-Ewoldt

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 September 2003 and 11 May 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

Claims 1-10 will be examined on the merits.

Claim Objections

Claim 1 is objected to because of the following informalities: the term "ageing" is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claim 1 is rendered vague and indefinite by the term "synergistic" because the specification does not adequately disclose amounts and/or proportions of the claimed ingredients necessary to provide such a synergistic effect- i.e., the metes and bounds of this term are not clearly delineated because the specification fails to adequately teach synergistic amounts/proportions thereof (please note that synergism is well known in the art to be an unpredictable phenomenon highly dependent upon specific amounts and/or proportions of active ingredients therein).

Claim 4 recites the limitation "the sodium salt" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7, 9-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. 6,627,231 B2. Claims 1-7 and 9-10 fall completely within the scope of claims 1-8 of US 6,627, 231 B2. Therefore the instant claims are "anticipated" by claims 1-8 of U.S. 6,627,231 B2 and thus constitutes double patenting.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7, 9-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Soldati (US 6,627,231 B2).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

A method of protecting the skin from UV rays or aging or inflammatory process by administering a composition comprising vitamin E, beta-carotene, vitamin C, selenium and extracts of *Vitis vinifera* and *Lycopersicum esculentum* is claimed.

Soldati expressly discloses using extracts of *Vitis vinifera* (grape) and *Lycopersicum esculentum* (tomato) combined with vitamins C and E, beta-carotene and selenium in protecting the cell by the overproduction of free radicals. In addition, the carrier material is soybean oil, fully or partially hydrogenated soybean oil, rape oil, peanut oil, lecithins (soy or egg), soyphosphatide and beeswax and administered in the form of soft or hard gelatin capsules, tablets, coated tablets, suppository or in transdermal form (see claims 1-8, for example).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would

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have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bombardelli *et al.* (US 5,648,377) in view of "Aim for Health" publication (2000) in light of Sepp (this reference is cited merely to relay an intrinsic property and is not used in the basis for rejection per se).

A method of protecting the skin from UV rays or aging or inflammatory process by administering a composition comprising vitamin E, beta-carotene, vitamin C, selenium and extracts of *Vitis vinifera* and *Lycopersicum esculentum* is claimed.

Bombardelli *et al.* discloses using extracts of *Lycopersicum aesculentum* (tomato) and *Vitis vinifera* (grape) in treating a patient suffering from inflammation due to the overproduction of free radicals. Bombardelli *et al.* does not disclose using vitamins E or C, beta-carotene or selenium in conjunction with the composition nor specifically disclose the claimed treatment regimens (see example 1 and claims 1-6).

The "Aim for Health" publication discloses it is common that vitamins A (beta-carotene), C and E and selenium are antioxidants that protect the skin from free radicals caused by UV rays from the sun. In addition, grape seed extract also contains antioxidants.

Sepp discloses that UV radiation induces the formation of free radicals (page 1, fourth paragraph).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the herbal agents discussed above for the following reasons. It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Sussman*, 1943 C.D. 518; *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

It would clearly have been obvious to one of ordinary skill in the art at the time the claimed invention was made to administer an effective amount (including within a conventional unit dosage- such as a tablet, capsule, etc.) of *Vitis vinifera* and *Lycopersicum esculentum*, or an extract thereof, to a subject suffering from inflammation or aging due to UV rays, based upon the beneficial teachings provided by the cited references, as discussed above. The adjustment of particular conventional working conditions (e.g., determining a result-effective amount of *Vitis vinifera* and *Lycopersicum esculentum*, or extract thereof for such purpose) is deemed merely a matter of judicious selection and routine optimization, which is well within the purview of the skilled artisan.

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From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Summary

No claim is allowed.

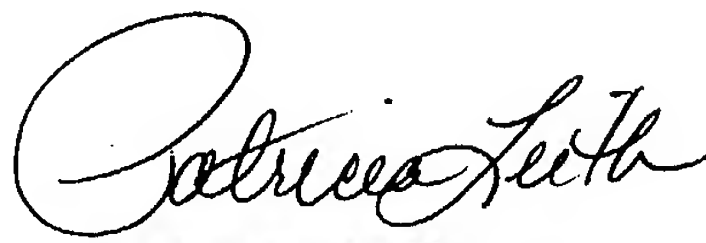
Future Correspondence

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Susan B. McCormick-Ewoldt whose telephone number is (571) 272-0981. The Examiner can normally be reached Monday through Thursday from 6:00 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The official fax number for the group is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

sbme


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PRIMARY EXAMINER